

# EXHIBIT D

Charles Hanes, II, M.D.

1 UNITED STATES DISTRICT COURT

2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

3 CHARLESTON DIVISION

4

IN RE: ETHICON, INC., \* MASTER FILE NO. 2:12-MD-02327

5 PELVIC REPAIR SYSTEM \* MDL 2327

PRODUCTS LIABILITY \* JOSEPH R. GOODWIN

6 LITIGATION \* U. S. DISTRICT JUDGE

7

THIS DOCUMENT RELATES TO ALL CASES.

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14 The deposition of CHARLES HANES, II, M.D.,  
15 taken at Helmsing, Leach, Herlong, Newman &  
16 Rouse, 150 Government Street, Suite 200,  
17 Mobile, Alabama, on the 12th day of July, 2019,  
18 commencing at approximately 9:30 a.m.

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24

Charles Hanes, II, M.D.

1 A P P E A R A N C E S

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LOIS ANNE ROBINSON, RPR, RDR, CRR

COURT REPORTER

Charles Hanes, II, M.D.

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Charles Hanes, II, M.D.

1 (EXHIBITS 1 THROUGH 6 WERE

2 MARKED FOR IDENTIFICATION.)

3 CHARLES HANES, II, M.D.,

4 the witness, after having first been

5 duly sworn to tell the truth, the whole truth,

6 and nothing but the truth, was examined and

7 testified as follows:

8 EXAMINATION

9 BY MS. WATKINS:

10 Q Good morning, Doctor.

11 A Good morning.

12 Q Can you hear me okay?

13 A I can.

14 Q Okay. As we discussed before we went  
15 on the record, I am attending by phone, so if at  
16 any point you cannot hear me, will you please let  
17 me know?

18 A I certainly will.

19 Q Okay. And if you don't understand any  
20 of my questions, will you please let me know?

21 A Certainly.

22 Q Okay. And you've done a report setting  
23 forth your opinions regarding the Prolift and the  
24 Prolift + M; correct?

1 A Correct.

2 Q At this time, do you have any changes  
3 or additions to your Prolift report?

4 A Not at this point. Yes.

5 Q Okay. And you've also done a report  
6 setting forth your opinions on the TVT, the  
7 TTVT Obturator, the TTVT EXACT, and the TTVT  
8 ABBREVO; correct?

9 A Correct.

10 Q And do you have any changes or  
11 additions to that report at this time?

12 A No.

13 Q Okay. And have you seen the deposition  
14 notice for your deposition here today?

15 Yes.

16 MS. WATKINS:

17 Q And, Madam Court Reporter, Miss Lois,  
18 have we marked that as an exhibit yet?

19 THE COURT REPORTER:

20 Not yet. I'll make it Number 7.

21 (EXHIBIT NUMBER 7 WAS  
22 MARKED FOR IDENTIFICATION.)

23 MS. WATKINS:

24 Number 7.

Charles Hanes, II, M.D.

1 Q The court reporter has marked the  
2 Notice of Deposition as Exhibit 7. And have you  
3 seen Exhibit A, Doctor, to that notice, which is  
4 on page 6 that's titled "Schedule A"?

5 MR. BARTON:

6 And, Diane, just for the record, we did  
7 file, I think, objections and responses to the  
8 deposition notice and documents requested, and  
9 you should have received that. Did you receive  
10 that?

11 MS. WATKINS:

12 I believe so. Understood.

13 MR. BARTON:

14 Okay. Great.

15 A So, yes. I'm looking at page 6.

16 MS. WATKINS:

17 Q Okay. Have you brought the responsive  
18 materials with you here today?

19 A Yes.

20 Q Okay. And what have you brought to the  
21 deposition?

22 A We brought a CV, the general documents,  
23 the invoice, and the -- yeah, the copy of the  
24 general reference materials.

1 Q Okay. And, for the record, I  
2 believe -- and correct me if I'm wrong, please --  
3 that we've marked the flash drive. It was  
4 Exhibit 1.

5 A Yes.

6 Q Is that correct?

7 A Was that Exhibit 1? Yes.

8 Q And does the flash drive contain the  
9 reliance materials for your Prolift and TVT  
10 reports?

11 A It appears to, yes.

12 Q Okay. And have we marked your invoice  
13 as Exhibit 2?

14 A Yes.

15 Q Okay. And I want to talk for a minute  
16 about the invoice. The invoice appears to have  
17 two line items, one pertaining to your Prolift  
18 report and one pertaining to your TVT report.

19 Correct?

20 A Correct.

21 Q And the first line item lists 5-11  
22 through 5-17, preparation of TVT report, 25.4  
23 units, \$450 cost per unit, which equals  
24 \$11,430.00; correct?

1 A Yes.

2 Q Okay. I assume the units are the hours  
3 spent? Is that correct?

4 A That is correct.

5 Q And does the preparation of the TTVT  
6 report include reviewing materials or simply  
7 drafting the report?

8 A Reviewing materials.

9 Q Okay. And drafting it?

10 A Correct.

11 Q Okay. And, then, so I assume the 5-11  
12 through 17, was that May 11th through May 17th  
13 working on it?

14 A Yes.

15 Q Okay. And then the next line item is  
16 May 17th through 26th, preparation of Prolift  
17 report. And, so, did you spend 18.4 hours  
18 reviewing materials and preparing the Prolift  
19 report?

20 A I did.

21 Q Okay. And that cost per unit for both  
22 of those reports was \$450 per hour?

23 A Correct.

24 Q Okay. So for Prolift, the total amount

Charles Hanes, II, M.D.

1 was \$8,280.00; correct?

2 A Correct.

3 Q So for your TVT -- or for the TVT time,

4 referring to the TVT family of products that

5 you've included in your report, for the TVT and

6 Prolift report, your review of materials and then

7 drafting the report, the --

8 Well, strike that.

9 The total amount that you've spent for

10 those two reports is contained within those

11 invoices. Is that -- or that invoice. Is that

12 correct?

13 A That is correct.

14 Q Okay. And, then, is your CV, which

15 we've marked as Exhibit 3, current as of today?

16 A Yes, it is.

17 Q Okay. And I noticed -- we noticed

18 your -- or -- excuse me -- we marked your general

19 materials list as Exhibit 4, but I was provided

20 with a supplemental materials list a couple days

21 ago. Have you been provided with that

22 supplemental list?

23 A I'm not aware of that.

24 Q Okay. And does the general materials

Charles Hanes, II, M.D.

1 list that you have, marked as Exhibit 4, apply to  
2 both the Prolift report and the TVT report?

3 A I believe so, yes.

4 Q Okay. When were you first contacted by  
5 Ethicon's counsel regarding serving as a general  
6 causation expert in the Ethicon litigation?

7 A It was -- I would think it was either  
8 right at the end of April or the beginning of  
9 May.

10 Q Of 2018?

11 A Yes. No. 2019.

12 Q Okay. And we talked a little bit about  
13 your invoice. Have you or are you going to bill  
14 Ethicon anything in addition to the invoice that  
15 you've marked as Exhibit 2 for your services as a  
16 general causation expert in the Ethicon  
17 litigation?

18 A I'll bill them for our time today and  
19 preparation for this deposition.

20 Q Okay. How much time did you spend  
21 preparing for the deposition?

22 A Three hours.

23 Q And when was that?

24 A Yesterday evening, or afternoon.

1 Q And what did you do to prepare?

2 A Mr. Barton and I spent some time  
3 discussing the materials.

4 Q Did you meet with Mr. Barton for three  
5 hours?

6 A Yes.

7 Q Aside from meeting with Mr. Barton and  
8 reviewing your reports, did you review anything  
9 else?

10 A No.

11 MS. WATKINS:

12 Madam court reporter, if you don't mind  
13 marking what I've emailed to you which is titled  
14 "Supplemental General Materials List" -- it has  
15 Dr. Hanes' name at the top -- as Exhibit 8, I  
16 would appreciate it, when you get a moment.

17 THE COURT REPORTER:

18 I do not have one named that, I don't  
19 think. I have other things, but I don't have  
20 that.

21 MS. WATKINS:

22 Okay. That's fine.

23 Q Okay. Dr. Hanes, aside from meeting  
24 with Dr. Barton -- excuse me -- Mr. Barton

Charles Hanes, II, M.D.

1     yesterday, have you had communications with  
2     counsel for Ethicon regarding this litigation?

3     A            Regarding these general reports or --  
4                   Be more -- what -- I'm not sure I  
5     understand.

6     Q            Well, you said your first contact was,  
7     I believe, in April of May of 2019. And, at that  
8     time, who was your contact person as far as  
9     Ethicon's attorney?

10    A            Jordan Walker.

11    Q            Okay. And did you have any phone  
12    conferences with Jordan Walker about the general  
13    expert reports that you were going to be  
14    drafting?

15    A            No, not --

16                   I mean, we've talked subse- -- we've  
17    talked a couple of times in the -- in the course  
18    of this whole process. But at the time of  
19    initial contact, it was just a request for me to  
20    do the general reports, and that -- that was it.

21    Q            Okay. Aside from the work that  
22    we've -- you've done for the general causation  
23    expert report, have you done any other work for  
24    the Ethicon transvaginal mesh litigation?

Charles Hanes, II, M.D.

1 A Yes. I've done some case-specific  
2 reports.

3 MR. BARTON:

4 And, Diane --

5 MS. WATKINS:

6 Q Do you know how many case-specific  
7 reports you've done?

8 MR. BARTON:

9 Diane, excuse me for a second, since  
10 you can't see me. Let me just interject an  
11 objection to "work for." I mean, he's a paid  
12 outside --

13 MS. WATKINS:

14 Understood. I can rephrase my --

15 MR. BARTON:

16 -- consultant.

17 MS. WATKINS:

18 I'll withdraw my question.

19 MR. BARTON:

20 Okay. Thank you.

21 MS. WATKINS:

22 Q Doctor, it's my understanding that you  
23 have been retained in certain cases to do  
24 case-specific reports in the Ethicon litigation.

1 Is that correct?

2 A Yes.

3 Q And how many cases have you been  
4 retained to do case-specific expert reports in  
5 the Ethicon litigation?

6 A I don't know the exact number, but it's  
7 probably close to a dozen, about a dozen.

8 Q Have you been deposed in those cases?

9 A I've been deposed on one.

10 Q Do you know the name of that case?

11 MR. BARTON:

12 Aldridge?

13 THE WITNESS:

14 Aldridge. Yeah. I think that's the --

15 MS. WATKINS:

16 Q Is that Margaret Aldridge? Does that  
17 ring a bell?

18 A I can't remember.

19 Q Okay. The only reason I asked is  
20 because that happened to be my case, and it was  
21 an Ethicon case.

22 Have you been deposed as a treating  
23 physician in any of the Ethicon transvaginal mesh  
24 cases?

Charles Hanes, II, M.D.

1 A No.

2 MR. BARTON:

3 Well --

4 THE WITNESS:

5 Oh, wait. Excuse me.

6 MS. WATKINS:

7 Q You said you have been deposed in the

8 Aldridge case?

9 MR. BARTON:

10 Diane, let me interrupt you, just to

11 help both of you, to be sure you're not

12 misunderstanding each other. You asked him if he

13 had ever been deposed as a treater?

14 THE WITNESS:

15 Treating physician.

16 MS. WATKINS:

17 Yes.

18 MR. BARTON:

19 As a treating physician. And you have

20 been deposed as an implanter.

21 MS. WATKINS:

22 Sorry. No. I'll rephrase.

23 MR. BARTON:

24 Right?

Charles Hanes, II, M.D.

1 MS. WATKINS:

2 Q **But you've been deposed in the Aldridge**  
3 **case; is that correct?**

4 A That's correct. And we're -- we're  
5 discussing. I may have been deposed as a  
6 treating physician, and I can't remember.

7 MR. BARTON:

8 Diane, I believe Dr. Hanes has been --  
9 And I don't want us to trip up on  
10 words. In our shop, we often refer to the  
11 doctors wearing different hats as maybe an  
12 implanter, an explanter, or just a treater --

13 MS. WATKINS:

14 Right.

15 MR. BARTON:

16 -- a treater being someone who didn't  
17 do surgery, didn't do an implant or an explant  
18 but just a treating physician. So I don't know  
19 if Dr. Hanes is confused with that language or  
20 y'all are on the same page or not.

21 But I think Dr. Hanes may have been  
22 deposed in this litigation as an implanter years  
23 ago.

24 MS. WATKINS:

1                   Okay. Fair enough.

2    MR. BARTON:

3                   But you need to clarify that with him.

4    MS. WATKINS:

5                   Some people do interpret the word

6    "treater" differently.

7    Q            Doctor, as an implanter or explanter or  
8    treater of a transvaginal mesh plaintiff, have  
9    you been deposed for purposes of litigation?

10   A           I honestly can't remember. I'm sorry.

11   Q           Okay. Fair enough.

12               And, Doctor, you are -- you know, I  
13   think Ethicon's counsel may have informed you.  
14   If you do not remember or you do not know the  
15   answer, you are able to say that.

16   A           Okay. Yeah.

17   Q           I appreciate your answer, though.

18               And we talked a little bit about your  
19   invoice. Is your fee schedule for review and  
20   preparation of reports \$450 per hour?

21   A           Yes.

22   Q           And -- and is that the same price for  
23   deposition testimony?

24   A           Yes.

Charles Hanes, II, M.D.

1 Q And do -- what about trial testimony?

2 A Thus far, I've not been to trial. But  
3 I think -- I think that the charge is \$5,000 per  
4 day.

5 Q Okay. Have you ever testified at any  
6 trial for any purpose, meaning not even -- not  
7 limiting it to transvaginal mesh. Any trial.

8 A I don't believe so, no.

9 Q Okay. And is your charge for  
10 consultation and meeting with counsel \$450 per  
11 hour?

12 A Yes.

13 Q So aside from your meeting with  
14 Mr. Barton yesterday, the invoice that we've  
15 marked as Exhibit 2 is what you've billed for the  
16 Ethicon litigation thus far. Is that correct?

17 A For the preparation of the general  
18 reports.

19 MR. BARTON:

20 In this case.

21 THE WITNESS:

22 Yeah, in this case.

23 MS. WATKINS:

24 Q Right.

Charles Hanes, II, M.D.

1                   And, then, aside from any meeting with  
2   Mr. Barton, have you done anything else for the  
3   Ethicon litigation that you intend to bill for?

4   A               The case-specific reports, as -- you  
5   know, if any further arise.

6   Q               Okay. And if there's moments of  
7   silence, Doctor, it's just because I'm going  
8   through my outline and crossing things off. So  
9   just as an FYI. I have not checked out. Just  
10   notes on my outline.

11                  Have you been paid for the amount that  
12   you've billed on the invoice that we've marked as  
13   Exhibit 2?

14   A               Not to date.

15   Q               Okay. Have you served as an expert  
16   witness for any transvaginal mesh manufacturer?

17   A               No.

18   Q               And is that true with respect to  
19   case-specific as well?

20   A               Correct.

21   Q               Have you been deposed as a treater,  
22   implanter, or explanter in any transvaginal mesh  
23   case against a manufacturer other than Ethicon?

24   A               No, I have not.

1 Q Okay. Have you given a deposition in a  
2 transvaginal mesh case prior to today, aside from  
3 the one that you mentioned, which I believe is  
4 Aldridge?

5 A No, I don't believe so.

6 MR. BARTON:

7 What you said is you can't remember.

8 THE WITNESS:

9 Yeah. I can't be certain about that,  
10 but I can't recall another one.

11 MS. WATKINS:

12 Q Have you talked to any Ethicon  
13 employees in conjunction with forming your  
14 opinions in the transvaginal mesh litigation?

15 A No, I have not.

16 Q Aside from your expert work for  
17 purposes of the transvaginal mesh litigation,  
18 have you been a consultant for Ethicon?

19 A I have.

20 Q Okay. And Lois will have some  
21 consulting agreements in front of her.

22 And, Lois, if you don't mind marking  
23 those. I believe that there are five consulting  
24 agreements that we could locate. So if you don't

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1 mind, Lois, start off with the earliest, which is  
2 the February 2007 consulting agreement, and  
3 marking those 9, 10, 11, 12, 13.

4 (EXHIBITS 8, 9, 10, 11, AND 12

5 WERE MARKED FOR IDENTIFICATION.)

6 MS. WATKINS:

7 Q Doctor, the earliest consulting  
8 agreement that we could find was February 2007.  
9 Do you believe that that was when you first  
10 started working as a consultant for Ethicon or do  
11 you believe that it might be sooner than that?

12 A I think it was -- I think it was sooner  
13 than that.

14 Q Okay. When do you think you first  
15 became a consultant for Ethicon?

16 A I think it was 1999 or possibly 2000.

17 But it was right -- right in that neighborhood.

18 Q In '99 or 2000, what was your role as a  
19 consultant for Ethicon?

20 A I became a preceptor for instructing  
21 physicians on the use of the TVT.

22 Q The TVT retropubic?

23 A Yes.

24 Q And do you recall how much -- what the

1 compensation agreement was at that time?

2 A Diane, I think -- I think it was a  
3 thousand dollars per physician trained.

4 Q Did the physicians come to you and  
5 observe you doing the procedure?

6 A They came to me, and they -- we did a  
7 multiple kind of training episode. We had access  
8 to a cadaver lab, which we took them to, and  
9 instructed them on the use, in the cadaver  
10 setting, and then we went and they watched live  
11 surgery. And then we had a didactic along with  
12 that.

13 Q Was that there in Mobile or was that in  
14 New Jersey or elsewhere?

15 A No. That was in Mobile.

16 Q Okay.

17 A And we used the University of South  
18 Alabama Medical Center Department of Anatomy for  
19 the cadaver lab.

20 Q Okay. So from 1999 to 2000 on, did you  
21 have an annual contract with Ethicon up until a  
22 certain period of time, to your knowledge?

23 A Yeah. I think it was an annually  
24 renewable contract.

Charles Hanes, II, M.D.

1 Q As a preceptor?

2 A Yes.

3                   Actually, it says on here -- it says on  
4 this one I'm looking at "Extend for a period of  
5 one year with automatic renewals for an  
6 additional two years." So I guess the contract  
7 was rewritten every two or three years.

8 Q               Okay. So when was the last time you  
9 served as a preceptor for Ethicon?

10 A              I think it was in 2012. Maybe 2011,  
11 but right in that...

12 Q              Okay. So is it your memory that from  
13 1999 or 2000 to 2011 or 2012, you were a  
14 preceptor for Ethicon during those years?

15 A              Yes.

16 Q              And aside from the TVT retropubic, are  
17 there any other products that you were a  
18 preceptor for?

19 A              I became -- as soon as they added the  
20 TVT-O, then I was a preceptor for that. And then  
21 once the Prolift products came on board, I became  
22 a preceptor for them as well. It wasn't -- it  
23 wasn't immediately after their introduction, but  
24 it was maybe a year after they were on the

Charles Hanes, II, M.D.

1 market, or thereabouts.

2 Q Okay. Were you a preceptor for the TVT  
3 EXACT?

4 A I don't remember exactly when the EXACT  
5 came on board. But if it came on board before  
6 2011, then I was.

7 Q Okay. And, then, what about the  
8 TVT ABBREVO?

9 A Yes.

10 Q And what about the TVT SECUR?

11 A No. I never -- I never was a preceptor  
12 for that.

13 Q Were you a preceptor for the  
14 Prolift + M?

15 A Yes.

16 Q And did your compensation increase from  
17 the thousand dollars per doctor, which was your  
18 memory, from 2000 or -- excuse me -- 1999, 2000,  
19 to 2011, 2012, did this increase over time?

20 A No, it did not.

21 Q Okay. I want to look a little bit  
22 about the consulting agreements that we were able  
23 to find. Obviously, there are totally some of  
24 them out there that we couldn't find. But the

1 first is dated February 9th, 2007, which we've  
2 marked as Exhibit 9, I believe.

3 A Yes.

4 Q Do you have that in front of you,  
5 Doctor?

6 A I do.

7 Q Okay. If you don't mind just turning  
8 to --

9 In the bottom right corner, you'll see  
10 that the parties have marked these documents with  
11 what we call Bates numbers, and the last three  
12 are 169.

13 A 169?

14 Q Uh-huh.

15 And let me know, please, when you get  
16 to that page.

17 A I don't see the Bates number. Do you?

18 MR. BARTON:

19 Diane, these copies do not appear to be  
20 Bates-labeled.

21 MS. WATKINS:

22 Really.

23 MR. BARTON:

24 Yeah. Sorry about that, but I don't

Charles Hanes, II, M.D.

1 see that.

2 MS. WATKINS:

3 The bottom right corner?

4 THE WITNESS:

5 No.

6 MS. WATKINS:

7 They're the same ones I sent the court  
8 reporter, the same ones I printed out.

9 THE COURT REPORTER:

10 They're the ones I printed out.

11 THE WITNESS:

12 Which page do you want me to get to?

13 MS. WATKINS:

14 Q Well, it's the --

15 MR. BARTON:

16 Well, maybe they're in the lower left.

17 THE WITNESS:

18 Let's see.

19 MS. WATKINS:

20 Well, it's the -- look at the last page  
21 of the consulting agreement dated February 9th,  
22 2007.

23 MR. BARTON:

24 I don't think that's a Bates label.

Charles Hanes, II, M.D.

1 THE WITNESS:

2 Huh-uh.

3 MS. WATKINS:

4 And the paragraph numbers are 5, 6, 7,

5 8.

6 MR. BARTON:

7 So, Diane, I don't think these have the

8 Bates-labeled numbers on them. But we may be

9 able to follow along if you just identify the

10 page you want him to look at.

11 MS. WATKINS:

12 Q Okay. Well, it's the fourth page from

13 the last.

14 A Fourth page --

15 Okay. Is that the page that's got item

16 B at the bottom?

17 Q Yes.

18 A Okay.

19 Q Okay. I'm going to ask you a little

20 bit about paragraph 8. And that paragraph

21 describes the description of services as

22 participation in the 2007 Incontinence and Pelvic

23 Floor Summit held in St. Petersburg, Florida.

24 A Okay.

1 Q Do you see that, Doctor?

2 A Yes.

3 Q Do you recall attending that conference  
4 in St. Petersburg, Florida?

5 A I do.

6 Q And do you recall what your role would  
7 have been at that conference?

8 A The summit -- the summit meetings were  
9 meetings that Gynecare put on for all of the  
10 preceptors. And it was an annual meeting where  
11 the preceptors came together, together with the  
12 representatives from the company who were  
13 specifically relegated to the -- to these  
14 products, and it was a meeting -- it was a  
15 meeting that was put on really to, number 1,  
16 update us on any -- any developments, but number  
17 2 was to provide kind of a free-flowing forum for  
18 discussion on products, problems, recommendations  
19 of how to improve techniques, et cetera. You  
20 know, it's just a --

21 It was really a great meeting, in my  
22 opinion, because it was designed to further the  
23 betterment of the services that we delivered and,  
24 where applicable, improve on the products.

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1 Q Okay. And, based on your memory, did  
2 you attend the annual meeting from when you first  
3 started working as a preceptor in 1999 or 2000  
4 till when you last served as a preceptor in 2011  
5 or 2012?

6 A I think I -- yeah. I think --  
7 I can't remember a single one of those  
8 summit meetings that I missed. They were --

9 Q Okay.

10 A They were very excellent meetings, and  
11 I -- I really gained a tremendous amount from  
12 attending them.

13 Q And you mentioned a discussion at those  
14 meetings of problems. Do you recall any problems  
15 that were discussed regarding the transvaginal  
16 mesh product?

17 A I don't remember any generic problems.  
18 I mean, you know, people would have specific  
19 things that might have arisen and they would get  
20 feedback on. But I don't remember anything that  
21 was generic to the -- to the product, if that  
22 makes sense.

23 Q Yeah.

24 Do you remember anything specific to

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1 any of the products that was discussed?

2 A Oh, gosh. You know, I remember --

3 For example, I do -- I do recall that

4 there was discussion about this whole issue of

5 mesh contracture. And that was debated. And, to

6 the best of my knowledge, nobody really had

7 any -- any knowledge or experience of having that

8 problem.

9 I think the general agreement was

10 whenever -- whenever there's a scar, there's

11 gonna be a contraction of the scar. But it was

12 not a function of the mesh. It was a function of

13 the scar.

14 So it was just never really something

15 that --

16 You know, and we were getting reports

17 like, you know, there were mesh contractures of

18 50 percent. And that was, you know, outrageous.

19 I mean, nobody, including myself, ever

20 experienced anything like that. So it just --

21 You know, there were things that came

22 up that were being reported, and, so, we would

23 discuss those and try to -- try to come to -- to

24 the bottom of it and some, you know -- just

1 obtain the experiential evidence that we all  
2 brought together as a group of experts around the  
3 country.

4 Q Okay. And were, to your knowledge,  
5 were all of the attendees at these conferences or  
6 annual preceptors for Ethicon?

7 A Well, the -- the invited attendees,  
8 yes, were. Of course, the company representative  
9 attendees were there as well.

10 Q Okay. And over the course of your  
11 practice, including those meetings, have you  
12 formed an opinion as to whether mesh can contract  
13 after proper implantation?

14 A Yeah. I don't -- I don't -- I don't  
15 believe in --

16 Like I say, I mean, there is  
17 contraction associated with any scar. I mean,  
18 that's a property of healing and a property of  
19 scar formation. But contraction beyond that norm  
20 that's expected as a result of the implantation  
21 of the mesh I would disagree with.

22 Q Okay.

23 A And let me go -- can I go back a  
24 minute? You asked about the attendees. I mean,

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1 there were occasionally --

2 Like, I think that one time the product

3 developer, the inventor of the TVT-O,

4 Dr. de Leval, was there, and they would have

5 occasional guests like that who were, you know,

6 obviously related. They were physicians that

7 were related to the products.

8 Q Okay. Fair enough.

9 And, of course, throughout the

10 deposition, if you'd like to either supplement or

11 change an answer, feel free to do so. I

12 appreciate that.

13 And just so I have an understanding of

14 your opinion about mesh contracture or

15 contraction, is it --

16 And I'm not trying to be argumentative.

17 I just want to understand what your opinion is.

18 Is it your opinion that the mesh itself

19 does not contract; it is the scar tissue that

20 contracts?

21 A That's correct. I mean, with the --

22 with the implantation of mesh, you have tissue

23 incorporation. And, so, as that tissue is

24 incorporated and then that tissue becomes a part

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1 of the scarring that accompanies the incision,  
2 then it's going to -- to contract, but, again,  
3 not to any greater degree.

4 In fact, in my opinion, the tissue  
5 incorporation keeps the mesh from contracting.

6 It seems inconceivable to me that the mesh could  
7 contract beyond what the tissue and scarring is  
8 doing simply because the integration of the  
9 tissue with the mesh.

10 Q Okay. And when you attended these  
11 annual Ethicon conferences, were all of the  
12 products, meaning the TVT line of products and  
13 the Prolift line of products, discussed?

14 A Yes.

15 Q Okay.

16 Okay, Doctor. You can set aside  
17 Exhibit Number 9, and I'd like to move on to  
18 Exhibit Number 10, which is a consulting  
19 agreement from the same year, but it's March 1st,  
20 2007. Do you have that in front of you, Doctor?

21 A Yeah. I've got -- maybe the --

22 The first one, you said, was 9, and the  
23 one March 1, 2007, has the label 8 on it. So  
24 that was out of order. But...

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1 Q Okay. So that's been marked Exhibit 8?

2 A Yes. And the 10 is dated 2 -- February  
3 1, '09.

4 Q Okay. Okay. I appreciate that.

5 Okay. If you don't mind turning three  
6 pages in, where the first couple paragraphs are  
7 numbered 11 and 12?

8 A Got it.

9 Q Okay. And if you don't mind looking at  
10 paragraph 12, six lines from the bottom, there is  
11 a sentence that says -- that starts with "you  
12 shall not."

13 A Yes.

14 Q Do you see that, Doctor? I'm just  
15 going to read that into the record and ask if  
16 that's something that you agreed to with respect  
17 to this consulting agreement.

18 "You shall not make any representations  
19 relating to Company's products or to Company's  
20 clinical outcomes unless such representations  
21 have been reviewed and approved in advance by  
22 Company."

23 Did I read that correctly?

24 A Yes.

1 Q Okay. I'll represent to you that in  
2 each of the contracts that we've marked here  
3 today, that provision is included in there. Was  
4 that something you agreed to as a consultant for  
5 Ethicon?

6 A Yes.

7 Q Perfect.

8 And, then, if you don't mind turning to  
9 the -- it's called Exhibit A.

10 A I've got it.

11 Q It is six pages from the back.

12 Okay. And under A4, it says  
13 "Preceptor/Surgical Training," and it says,  
14 "Consultant shall allow visiting surgeons and  
15 visiting company sales representatives to observe  
16 surgical procedures involving the practice of  
17 professional education training the clinical uses  
18 of various Ethicon products, and to consult with  
19 consultants regarding such procedures applicable  
20 patient confidentiality and consent  
21 requirements."

22 Do you see that?

23 A I do. But on this particular copy, it  
24 does not put in -- after you said "involving the

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1 practice of the clinical uses of," but it  
2 doesn't -- doesn't write in those specifics that  
3 you said. And then it resumes, "and to consult  
4 with consultant regarding such procedures."

5 MR. BARTON:

6 Diane, it looks like it's blank.

7 MS. WATKINS:

8 Q Okay. And, Doctor, is this the  
9 preceptor training that you discussed earlier in  
10 your deposition?

11 A Yeah. I believe it is.

12 Q Okay. And when you were a preceptor,  
13 was that --

14 Well, strike that.

15 When you were a preceptor for Ethicon,  
16 were you a preceptor for the Prolift product as  
17 well as the TVT product?

18 A Yes.

19 Q And the bottom part of that paragraph  
20 states, "Consultant shall allow such visits on up  
21 to 15 occasions, and Company shall pay consultant  
22 2,000 for each such session per eight-hour day."

23 Do you see that?

24 A Okay. Again, they didn't have -- my

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1 copy doesn't have those blanks filled in, so --

2 Q **That is --**

3 A \$2,000.00 for each session per

4 eight-hour day. So it didn't have \$2,000.00.

5 And I think I told you earlier it's one thousand

6 per physician. But if that's what it says, then

7 that would be. Because I can't --

8 MR. BARTON:

9 Diane, the exhibit we're looking at is

10 blank.

11 MS. WATKINS:

12 That is weird.

13 Lois, off the record real quick,

14 please.

15 (OFF THE RECORD.)

16 MS. WATKINS:

17 Q **Okay. Doctor, we were off the record**  
18 **kind of clearing up some miscommunication about**  
19 **the agreement with Ethicon, Consultant Agreement**  
20 **dated March 1st, 2007, and it looks like you were**  
21 **compensated, under that agreement, \$2,000 for**  
22 **each section of the preceptor for the Ethicon**  
23 **products. Is that correct?**

24 A Correct.

1 Q And do you recall, on an annual basis  
2 starting in 1999 or 2000 to 2012, how much you  
3 were compensated by Ethicon for your consulting  
4 work on an annual basis?

5 A I do not.

6 Q Do you have a ballpark?

7 A Oh, gosh. No. I really don't.

8 Q Okay. Under the terms of this March  
9 2007 agreement, you were able to be compensated  
10 \$2,000 for each session up to 15, which would  
11 obviously be 30,000. Do you think that you would  
12 have reached that 30,000?

13 A I think I would have, yes.

14 Q Okay. You can set that one aside,  
15 Doctor.

16 And, then, we're now gonna move on to  
17 the consulting agreement dated February 1st,  
18 2009, which I thought was marked as Exhibit 11.  
19 But I'm clearly off on my exhibits, I think.

20 A Yeah. It's number 10.

21 Q Okay. Thank you.

22 A And 11, Exhibit 11 is 1-25-10.

23 Q Okay. Then I'm one off on all mine.

24 Okay.

1                   And, Doctor, we could not find any  
2    consulting agreement for the year 2008. Is it  
3    your belief and memory that, from when you first  
4    started working as a preceptor for Ethicon in  
5    1999 or 2000 to 2012, you were a preceptor every  
6    year?

7   A           Yes.

8   Q           Okay. And, so, there likely is a  
9    contract out there somewhere for 2008, based on  
10   your memory; is that correct?

11   A           I guess, unless -- you know, in this  
12   first paragraph, it says "automatic renewals for  
13   two years." So I don't know if that would mean  
14   that there wouldn't be another written contract.

15   Q           Okay. Understood.

16                Okay. If you don't mind turning to the  
17   third-to-the-last page, which my copy, in the  
18   bottom right-hand corner, ends with 792. Let me  
19   know when you're there, please, Doctor.

20   A           Is that Exhibit A again?

21   Q           It is the third-from-the-last page.  
22   The bottom, in the right-hand corner, is 702, and  
23   it's the fourth paragraph, under Services and  
24   Fees.

1 A Is that "you and company"? Is that  
2 paragraph 20?

3 Q Paragraph 4. It's A4 under Exhibit A.

4 A Oh, I've gotcha. Okay. Oh, yeah.

5 Gotcha.

6 Q Okay. And this, again, discusses your  
7 preceptor role with Ethicon. And just to kind of  
8 circumvent additional questions, from the time  
9 you served as a preceptor starting in '99 or 2000  
10 to 2012, did you cover the TTV line of products  
11 as well as the Prolift products as a preceptor  
12 during all of those years?

13 MR. BARTON:

14 Object to the form.

15 Go ahead.

16 A I did.

17 MS. WATKINS:

18 Q Okay. And under the terms of this  
19 contract, in the summer of --

20 Excuse me. Strike that.

21 Under the terms of this contract from  
22 February 2009, you are to be compensated \$2,000  
23 for each session for an eight-hour day up to 12.  
24 Do you see that?

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1 A I do.

2 Q And do you think that you would have

3 reached that maximum of 24,000 for that year?

4 A Yes.

5 Q Okay. Let's look at the next page --

6 MR. BARTON:

7 Diane, can you hear me? This is Jim.

8 MS. WATKINS:

9 Yeah, Jim.

10 MR. BARTON:

11 Just let me interrupt for one second,  
12 because I may have misunderstood. And I  
13 apologize. And I apologize for interrupting if I  
14 have misunderstood. But was the prior question  
15 that you asked him whether he was a consultant  
16 for Ethicon for the TVT family of products as  
17 well as Prolift through the entire time he was a  
18 consultant for Ethicon? Because I don't --

19 That wouldn't be correct. You weren't  
20 a consultant for them on Prolift until it was --  
21 until it was available; right?

22 THE WITNESS:

23 Yeah. Till -- yeah, till after it was  
24 available. Yeah.

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1 MR. BARTON:

2 Till after it was available. And he

3 had asked and answered that previously.

4 Did I misunderstand your question and  
5 his answer, Diane? I just want to be sure you're  
6 not miscommunicating.

7 MS. WATKINS:

8 No, I -- that's fair. So I assume  
9 we're still on the record.

10 Q So, Doctor, from the time Prolift was  
11 available to when it was not available, when you  
12 were serving as a preceptor, was Prolift included  
13 as one of the products that you were a preceptor  
14 for?

15 A Again, I would -- I would say,  
16 basically, that's true. But I didn't -- I did  
17 not become a preceptor for Prolift immediately  
18 upon its introduction to the market. I was about  
19 a year into it before I became a preceptor.

20 Q Okay. Fair enough.

21 And, then, on the consultant agreement  
22 dated February 1st, 2009, if you don't mind  
23 turning to the second-to-last page, at the top  
24 it's paragraph 5, Advisory Board.

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1 A Yeah.

2 Q Let me know when you're there, Doctor.

3 Okay. And that states, in part,

4 "Consultant shall participate in various opinion

5 meetings organized throughout the year for

6 ProfEd," which would be Professional Ed,

7 "training."

8 Do you see that?

9 A Yes.

10 Q And it also states that "Company shall

11 pay consultant \$2,000 per eight-hour day for each

12 such meeting."

13 Do you believe that you did serve as a

14 consultant in these Professional Ed trainings for

15 \$2,000.00 per day?

16 A Yes.

17 Q And do you recall what your role would

18 be in those meetings?

19 The reason I ask, it seems to be

20 different than the preceptor paragraph.

21 A Yeah. I think it falls under two

22 categories. One -- one would be meetings that

23 were out of town in other locations where they

24 would put on a bigger meeting and invite

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1 potential user doctors to and have a large  
2 cadaver lab setting, and there would be a number  
3 of us preceptors who were there because of the  
4 volume of the -- the volume of attendants.

5 Q Okay.

6 A So that was one aptly -- one instance  
7 of that. And, then, another, I presume, by  
8 ProfEd -- I'm not --

9 Well, yeah. ProfEd training. Yeah.

10 So those were training meetings. So that would  
11 be it. Yeah. And there were a number of  
12 locations over the years that I went to to help  
13 put on those courses.

14 Q Okay. Were any of those overseas?

15 A No.

16 Q And, at the bottom of that page, the  
17 very last section, "The Parties agree that the  
18 compensation paid to consultant shall not exceed  
19 20,000" -- strike that -- "shall not exceed  
20 26,000 per year, except as may be mutually agreed  
21 in writing by the parties."

22 Do you have an understanding or memory  
23 of how much you would have received in 2009 with  
24 respect to that 26,000?

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1 A I don't specifically, but I -- I think  
2 that I probably maxed out on most of the years.

3 Q Okay. And, then, not to belabor this,  
4 but we have two more that we were able to find.

5 So if you don't mind turning to the next  
6 consulting agreement, which is dated  
7 January 25th, 2010.

8 A Correct.

9 Q Which I think you told me we've marked  
10 as Exhibit 11, I believe?

11 A Yes.

12 Q And if you don't mind turning to -- in  
13 the bottom right corner, it ends with 598, and it  
14 is four pages from the back.

15 A Yeah. Is that the Services and Fees  
16 again?

17 Q Yes, uh-huh.

18 A Okay.

19 Q Paragraph 1 is the Company-sponsored  
20 Speaker Program, which is checked "yes" now, and  
21 it says, "Consultant shall make such  
22 presentations on two occasions. The presentation  
23 will review pelvic floor repair and stress  
24 urinary incontinence."

1                   Do you see that?

2   A              Yes.

3   Q              And do you -- do you have a memory as  
4                   to what those speaker programs would have  
5                   involved?

6   A              Those were where I was invited to go  
7                   out of town and make a presentation to a  
8                   physician group.

9   Q              And looks like that, for each such  
10                   speaking engagement, you were paid \$3,000 per  
11                   eight-hour day plus out-of-pocket expenses.

12                  Correct?

13   A              Correct.

14   Q              Okay. And it also states in that  
15                   paragraph that there were two occasions that you  
16                   were to do that, which would obviously be \$6,000.  
17                  Do you think that you would have maxed out that  
18                   6,000?

19   A              Gosh, I -- you know, I don't know.  
20                  I -- I mean, when I think back on it, I can only  
21                   think of a couple of occasions where I went out  
22                   of town.

23                  Well, yeah. Maybe two or three or four  
24                   where I actually went out of town to do something

1 like that. So --

2 MR. BARTON:

3 Over all the years?

4 THE WITNESS:

5 Yeah, over all the years.

6 MS. WATKINS:

7 Q On those occasions you were paid the

8 \$3,000.00 per day plus out-of-pocket expenses?

9 A I presume, yes.

10 Q And you were still, if you look under  
11 paragraph 4, still doing the preceptor work, but  
12 in this year it looks like you had 16 occasions,  
13 paid at \$3,000.00 per session. Do you see that?

14 A Yeah. I do. I had forgotten that --

15 Q Did you want to --

16 A Yeah. I had forgotten that they went  
17 up on --

18 Q Yeah. I guess due to inflation, maybe.  
19 Do you think that you would have maxed that out  
20 for the 16 sessions at 3,000 per session?

21 A I -- I would guess I did.

22 Q Okay. And if you don't mind turning to  
23 the next page --

24 MR. BARTON:

1 Now, you're not supposed to guess. So  
2 if you don't remember, say you don't remember.

3 But don't guess.

4 MS. WATKINS:

5 Q It looks like you were also, under  
6 paragraph 8, it states, "Consultant shall perform  
7 other services designated below for dollar amount  
8 varies per hour," and it includes Faculty  
9 Training Meetings and Educational Summit/Forums.  
10 Negotiated rate to be no more than the maximum of  
11 \$375 rate/per hour."

12 Do you see that?

13 A I do.

14 Q Okay. And I assume those would have  
15 been the TVT family of products and the Prolift  
16 products. Is that correct?

17 A It would be.

18 Q Okay. And, then, the last line of that  
19 page states, "The parties agree that compensation  
20 paid to consultant shall not exceed \$60,000 per  
21 year except as may be mutually agreed in writing  
22 by the parties."

23 Do you think that you would have maxed  
24 out that \$60,000 per year in 2010?

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1 A I don't think I -- I don't think I ever  
2 got that much. But I -- I don't know for sure.

3 Q Do you have a memory as to the maximum  
4 amount per year, when you were working as a  
5 consultant for Ethicon, that you would have  
6 received?

7 A No, I don't.

8 Q Do you think that at any point you  
9 would have received \$60,000 per year from Ethicon  
10 working as a consultant?

11 A Like I said, I don't -- I don't -- I  
12 don't recall ever receiving that much. That  
13 seems like more than --

14 I could be wrong, but I don't remember  
15 that.

16 Q Okay. You can set that aside, and  
17 we'll go to the last one, which is dated  
18 February 1st, 2011.

19 A Yes.

20 Q Okay. And if you don't mind going to  
21 that Exhibit A, which in the bottom right corner  
22 is -- page is 267.

23 A Okay.

24 Q Again, company-sponsored speaking --

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1 speaker programs is checked, and it states that  
2 you shall make presentations on three occasions  
3 for \$3,000.00 per eight-hour day plus  
4 out-of-pocket expenses.

5 Do you believe that you would have  
6 maxed out those three occasions for 2011?

7 A I don't think so.

8 Q Okay. Well, why do you think that's  
9 not the case?

10 A I just don't recall doing three  
11 out-of-town meetings to -- for educational  
12 purposes. I -- I don't -- I don't recall ever  
13 doing that. I --

14 When I think back on it, you know, I  
15 can -- I can recall maybe three or four times  
16 over the course of the entire time that I went  
17 out of town to do a presentation.

18 MR. BARTON:

19 And how many years was that?

20 THE WITNESS:

21 Over a period of --

22 MS. WATKINS:

23 Q And, then, under the preceptor portion,  
24 it looks like, for the year 2011, "Consultant

1 shall allow such visits on up to 12 occasions and  
2 the company shall pay consultant \$3,000 for each  
3 session per eight-hour day."

4 Do you believe that you would have done  
5 the 12 occasions at \$3,000 per session?

6 A I think so.

7 Q Okay. And, if you don't mind, Doctor,  
8 please turn to the next page. Under Paragraph B,  
9 it says that your compensation paid to consultant  
10 shall not exceed \$51,000 per contract term. Do  
11 you believe that you would have maxed out the  
12 51,000 in 2011?

13 A I don't think so. I don't think I  
14 reached that number.

15 Q Okay. And, then, you mentioned that  
16 you were also a consultant with Ethicon in 2012.  
17 Do you recall your role -- we cannot find a  
18 contract for that. Do you recall your role as a  
19 consultant for Ethicon in 2012?

20 A Well, now, I'm not -- I'm not sure if I  
21 actually did any consulting in 2012. My -- my  
22 recollection is that the preceptor relationship  
23 terminated either late in 2011 or early in 2012.  
24 And I can't remember.

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1 Q Okay. Is there a reason why it  
2 terminated?

3 A Well, that was when the products, the  
4 Prolift products were removed from the market.  
5 And by that time, there really wasn't any need  
6 for training on the TVT products because they had  
7 been so universally adopted. It'd become  
8 products of choice and, you know, in a lot of  
9 people's view, the gold standard.

10 Q Okay. And I should have asked you this  
11 at the beginning of this line of questioning, but  
12 what led to you becoming a consultant for  
13 Ethicon?

14 A I'm sorry. What?

15 Q What led to you becoming a consultant  
16 for Ethicon? Like, how did that come about?

17 A That came about because, very early on  
18 after the introduction of the product, I -- I  
19 got -- I can't remember exactly, but I think that  
20 I went to a meeting and I was -- was very  
21 infatuated with the concept, and I ended up going  
22 to a company-sponsored cadaver lab for training  
23 purposes, and I quickly embraced the product  
24 because at that point in time the incontinence

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1 procedures I was doing were the Burch procedures  
2 through open incision, and I also had done a few  
3 laparoscopic Burches.

4 But -- but the simplicity of the TVT,  
5 the midurethral sling, that whole concept was so  
6 appealing because of being minimally invasive,  
7 and the preliminary data that was coming out of  
8 Europe that was available to us was very  
9 encouraging in terms of efficacy.

10 And, so, I got on board pretty quickly.

11 And, because of that, I -- and I -- I was asked  
12 and I expressed an interest in becoming a  
13 preceptor just because I believed so much in the  
14 product.

15 As soon as I began using it, the  
16 feedback I was getting from my patients totally  
17 reinforced all of the good reports that I was --  
18 I was hearing. And, so, I was pretty  
19 enthusiastic about it.

20 Q Okay. And have you been a consultant  
21 for any other transvaginal mesh company?

22 A I have not.

23 Q Okay. If you guys are okay with it,  
24 we've been going about an hour and 20 minutes.

1 Maybe we can take a 5-minute break for the  
2 bathroom?

3 A Sure.

4 Q Okay. I'll be back in five.

5 (BRIEF RECESS.)

6 MS. WATKINS:

7 Q Okay, Doctor. We're back on the record  
8 from a short break. And I asked you some  
9 questions at the beginning of the deposition  
10 about a supplemental general materials list that  
11 I was served with a couple of days ago. And, as  
12 we sit here today, it's my understanding that you  
13 have not seen that. Is that correct?

14 A Oh, no. I've seen the general  
15 materials list.

16 Q Okay. I received a supplemental one.

17 A Oh, the supplemental. Yeah. No, I --  
18 I don't think I've seen that.

19 Q Okay. So, as we sit here today, your  
20 general materials list is your reliance list;  
21 correct?

33 A Correct

23 Q And does it include everything that you  
24 are relying on in forming your general causation

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1   opinions in this litigation?

2   A           It does.

3   Q           Did you prepare that reliance list?

4   A           No, I did not.

5   Q           Do you have an understanding as to who  
6   prepared it?

7   A           I believe it was prepared by Butler  
8   Snow, but I -- I'm not certain.

9   Q           Okay. Is it your understanding that  
10   Butler Snow picked the materials listed on the  
11   reliance list?

12   MR. BARTON:

13              What was the question?

14   A           Say -- repeat that, please.

15   MS. WATKINS:

16   Q           Yes.

17              Do you have an understanding as to who  
18   picked the materials listed on the reliance list?

19   A           I don't -- I don't know who -- who was  
20   responsible for that.

21   Q           Have you reviewed every item on the  
22   materials list?

23   A           No.

24   Q           Did you review any Ethicon corporate

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1 documents in forming your general causation

2 opinions?

3 A I did not specifically review any

4 Ethicon documents.

5 Q Did you review any depositions in  
6 forming your general causation opinions in this  
7 litigation?

8 A I reviewed some of the other general  
9 reports, general expert reports on these  
10 products. I did.

11 Q Okay. Did you review any deposition  
12 testimony?

13 A In preparing these documents, no, I did  
14 not.

15 Q Okay. Bear with me, Doctor.

16 Did you ask to see any Ethicon  
17 corporate documents before preparing your general  
18 causation reports?

19 A No.

20 Q Did you ask to review any depositions  
21 of any corporate witnesses before preparing your  
22 reports?

23 A No.

24 Q Have you at any point reviewed any

1 medical literature that has called into question  
2 the safety of Ethicon transvaginal mesh products?

3 A I've reviewed tons of literature that  
4 have referred to the products, as well as  
5 potential problems and complications, just in the  
6 course of my career, yes.

7 Q Okay. Have you reviewed any medical  
8 literature that indicates that, after a proper  
9 implantation, the mesh used in Ethicon's TVT-O  
10 and ProLift products can degrade?

11 A I've seen claims to that effect, but I  
12 have not --

13 Well, I've seen some of the plaintiffs'  
14 expert witnesses' reports that have alleged that.  
15 I -- in my personal experience, I -- I don't  
16 believe any of that. It just doesn't hold water  
17 with me.

18 Q Okay. So, just so that I have an  
19 understanding, as far as medical literature, have  
20 you seen any medical literature indicating that  
21 Ethicon's mesh can degrade after a proper  
22 implantation?

23 A No, I have not.

24 Q Have you seen any medical literature

1 indicating that a properly placed Ethicon mesh  
2 product can rope or curl after implantation?

3 A I can't say that I've seen any  
4 literature that has said that.

5 Q Have you seen any medical literature  
6 indicating that a properly placed Ethicon mesh  
7 product can shrink or contract after  
8 implantation?

9 A You know, I can't specifically recall  
10 that. As I mentioned earlier, those were  
11 certainly points of discussion. But I -- I can't  
12 recall a specific article, for example, that  
13 would have elaborated on that.

14 Q Okay. Have you reviewed any medical  
15 literature indicating that a properly placed  
16 Ethicon mesh product can migrate after  
17 implantation?

18 A No.

19 Q Have you seen any medical literature  
20 indicating that a properly placed Ethicon mesh  
21 product can bunch up after implantation?

22 A No.

23 Q And only two more. Have you seen any  
24 medical literature indicating that a properly

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1 placed Ethicon mesh product can harden or stiffen  
2 after implantation?

3 A No.

4 Q Have you seen any medical literature  
5 indicating that a properly placed Ethicon mesh  
6 product can fray after implantation?

7 A No.

8 Q Switching gears slightly, do you know  
9 whether the mesh used for the TVT line of  
10 products is mechanical cut, laser cut, or both?

11 A Yes.

12 Q Okay. What is your understanding as to  
13 that?

14 A Well, the mechanical cut is -- is,  
15 like, cut with scissors or a knife; whereas,  
16 laser cut uses a laser. The mechanical cut has  
17 edges that aren't necessarily intact. They may  
18 have loose ends on the edges. Whereas, the laser  
19 cut is -- it doesn't. All the edges -- each  
20 little fiber comes together. And there are  
21 properties of -- the laser cut's generally a  
22 little bit stiffer in its physical properties.  
23 But those are the main things that stand out to  
24 me.

1 Q Do you have an understanding as to  
2 whether there's any difference with respect to  
3 the risks associated with a mechanical cut versus  
4 laser cut?

5 A I am not aware, and I don't believe  
6 there are any difference in risks.

7 Q And if I were to ask you the same thing  
8 with respect to the Prolift product, would your  
9 answers be the same?

10 A Yes.

11 Q Okay. Have you reviewed any Ethicon  
12 corporate documents indicating that physicians  
13 reported to Ethicon that its mechanical-cut mesh  
14 had properties similar to a Scotch Brite pad?

15 A I haven't seen anything to that effect.

16 Q Okay. Have you reviewed any medical  
17 articles that have discussed the edges of the TVT  
18 and Prolift mesh being abrasive and sharp?

19 A Say the question again, please.

20 Q Sure.

21 Have you reviewed any medical articles  
22 that have discussed the edges of the TVT and  
23 Prolift mesh being abrasive and sharp?

24 A I have not seen any medical literature

Charles Hanes, II, M.D.

1 that says that.

2 Q Okay. I want to switch gears a little

3 bit and talk about your own use of transvaginal

4 mesh products. Over the course of your practice,

5 what transvaginal mesh products have you used to

6 treat stress urinary incontinence and pelvic

7 organ prolapse in women?

8 A I've used the Ethicon products;

9 specifically, the retropubic TVT, the TVT EXACT,

10 the TVT-O, the TVT ABBREVO. I used the TVT SECUR

11 briefly.

12 And then I have used some of the other

13 products. Like, I believe I tried the

14 single-incision AMS product. And I can't

15 remember the brand name of that. But I didn't --

16 I didn't like it. I -- I may have --

17 And, then, I am currently using a

18 product by Coloplast that's called the Altus

19 midurethral sling.

20 Q Okay. And have you used any

21 transvaginal mesh product to treat pelvic organ

22 prolapse?

23 A I've used the ProLift products, all of

24 the ProLift products, anterior, posterior, total,

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1 Prolift, Prolift + M. I've used the Boston  
2 Scientific Uphold. I have tried the Boston  
3 Scientific -- I think it was the Pinnacle, maybe.  
4 But, again, I -- any deviation I made  
5 from the Prolift products was really just  
6 experimental to see whether or not I felt like  
7 they were as good as the Prolift products. And,  
8 so, I --

9 But that was the extent of it. I  
10 thought the Prolift products were excellent  
11 products and did what I expected them to do and  
12 gave me the results that I expected them to give.

13 Q And when was the last time you  
14 implanted a product from the TVT line of  
15 products?

16 A Probably within the last several  
17 months.

18 Q And you mentioned that you currently  
19 implant the Coloplast Altus. Is that your first  
20 choice currently in treating stress urinary  
21 incontinence in women --

22 A It is.

23 Q -- currently?

24 A Yes.

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1 Q Why is that?

2 A It's because it's a single-incision  
3 sling, which I had totally sworn off until it  
4 came on the market, because I had tried  
5 periodically -- I tried the TVT SECUR, I tried  
6 this AMS product, and I didn't like them because  
7 they were not adjustable. In other words, you  
8 could insert them and tighten them up, but if you  
9 determined that they needed to be looser, you  
10 couldn't loosen them without taking them out.

11 And this Altus sling is a totally  
12 adjustable midurethral sling that's in the same  
13 conformity as a transobturator approach, and you  
14 can tension it or loosen it. So it has  
15 everything I like, and it's minimally invasive.

16 It's -- I had --

17 My product of choice had become the TVT  
18 ABBREVO, which I think is an excellent product,  
19 as I also think the TVT EXACT is an excellent  
20 product. But -- but the Coloplast, because of  
21 its even less-invasive properties, is why I have  
22 embraced it.

23 Q Okay. In your current practice, what

24 treatment --

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1                   Well, strike that.

2                   In your current practice, what surgical  
3                   treatment options do you use to treat pelvic  
4                   organ prolapse?

5   A               I use a variety. I use -- if it's a  
6                   reconstructive procedure, then I -- the native  
7                   tissue repairs that I do are the anterior and  
8                   posterior colporrhaphies, the apical suspension  
9                   procedures or uterosacral ligament suspension,  
10                  and sacrospinous ligament suspension.

11                  And then I do, if I feel like mesh is  
12                  appropriate, then I do a sacrocolpopexy that I do  
13                  transvaginally.

14   Q               Okay. Do you also do abdominal  
15                  sacrocolpopexies?

16   A               I don't.

17   Q               Okay. Why is that?

18   A               Because the vaginal sacrocolpopexy is  
19                  better.

20   Q               Okay. And can you explain why it's  
21                  better?

22   A               Yeah. That's a very biased statement.  
23                  But it, in my opinion, it's -- it is better  
24                  because it's a more direct, less invasive

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1 procedure, shorter operating times, less  
2 morbidity, and gives full access to the anterior  
3 and posterior compartments, as well as the apex,  
4 so that a concurrent anterior/posterior repair  
5 becomes a natural part of the procedure.  
6 Whereas, with the abdominal approach, most  
7 people, if they need an additional rectocele  
8 repair, for example, they would do their  
9 abdominal colpopexy and then come below and do a  
10 separate incision for the rectocele repair. So  
11 that --

12 That's pretty much my answer. I mean,  
13 I think -- I think it's a superior operation.

14 Q           Okay. And do you, out of those  
15 treatment options, do you consider one of them to  
16 be the gold standard for the treatment of pelvic  
17 organ prolapse in women?

18 A           Well, I think your question needs to be  
19 more specific as to where the prolapse is. I  
20 mean, if it's --

21           I don't know if you want to specify. I  
22 mean, the heart of prolapse repair is the apex.  
23 And I -- I presume that you're comfortable with  
24 that. I mean, you can do anterior and posterior

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1 repair, and everybody does. But, you know, if  
2 the apex is not well suspended, then your  
3 repair's gonna fail.

4 So, in my opinion, the way I would  
5 answer your question is limiting it to apical  
6 repairs, apical suspensions. And I think the  
7 gold standard is universally recognized as the  
8 sacrocolpopexy.

9 Q Okay. And is that treatment option as  
10 effective as the **Prolift** product?

11 A I think it's as effective, yes.

12 Q And is it as safe as the **Prolift**  
13 product?

14 A I think that they're all safe,  
15 relatively safe. I mean, you know, every  
16 operation has its peculiarities, and -- but I --  
17 in my -- in my hands and in my experience,  
18 they're all -- the safety profile is very  
19 acceptable.

20 Q Okay. Are there risks associated with  
21 the **Prolift** product that are not associated with  
22 the sacrocolpopexy?

23 A You know, that's a --

24 Yeah. I think every operation has

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1      peculiarities, specific nuances that may make its  
2      risks a little bit different. But, all in all, I  
3      would say the risks are very comparable between.

4      Q           Hello?

5      A           I -- you want me to go a little bit  
6      further into that?

7      Q           Oh, no. I'm sorry. I didn't know if  
8      the phone cut out. I just wanted to make sure  
9      you were done with your answer, Doctor.

10     A           So I -- I think that, you know, the  
11     risks associated with Prolift are risks that are  
12     pretty much associated with any -- with the  
13     sacrocolpopexy, for example. I think -- I think  
14     they're very comparable.

15                In fact, actually, let me -- let me  
16     back up a little bit. I think that in today's  
17     world, and, actually, in the world that we were  
18     in during those years of Prolift, the abdominal  
19     sacrocolpopexy was frequently done as an open  
20     procedure. The laparoscopic approach was done by  
21     those who were well trained and able to do  
22     laparoscopic -- complex laparoscopic surgery with  
23     the knot tying. The robot hadn't really come  
24     into play.

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1                   So I would say that the large majority  
2                   of sacrocolpopexies at that point in time were  
3                   done as -- through open incisions. And,  
4                   therefore, the morbidity associated with that was  
5                   significantly higher -- significantly higher --  
6                   than the Prolift procedures.

7                   Prolift, because it's minimally  
8                   invasive compared to the sacrocolpopexy, had a  
9                   much lower morbidity.

10   Q            **Okay. Is a risk associated with**  
11   **Prolift that is not associated with the**  
12   **sacrocolpopexy mesh erosion?**

13   A            No. You could have mesh erosions with  
14   sacrocolpopexy, too.

15   Q            **Okay.**

16   A            Yeah. That's a very accepted risk.

17   Q            **Okay. In your current practice, we**  
18   **talked about some of the transvaginal mesh**  
19   **treatment options you use to treat stress urinary**  
20   **incontinence, but do you have any other treatment**  
21   **options that you use to treat stress urinary**  
22   **incontinence?**

23   A            I occasionally will do a Burch  
24   procedure, but I probably don't do more than

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1 one -- one a year, if that.

2 Q Is the Burch procedure a safe surgical  
3 treatment option to treat stress urinary  
4 incontinence in women?

5 A It's -- well, it's -- I mean, when you  
6 say "safe," it -- it has its own set of potential  
7 complications. It's much more invasive than the  
8 midurethral sling, and, because of that, it's not  
9 as safe, I guess --

10 I mean, if safe includes increased  
11 morbidity, which, in my mind, it does, then I  
12 would say it's not as safe as a midurethral  
13 sling.

14 Q But, just generally speaking, is it a  
15 safe procedure that you feel comfortable using to  
16 treat stress urinary incontinence in your  
17 patients even though it's --

18 A Yes.

19 Q -- infrequently?

20 Okay. Do you keep a patient registry  
21 for the patients in whom you have implanted  
22 transvaginal mesh products?

23 A No.

24 Q So is it fair to say that you can't say

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1 with accuracy what your complication rates are  
2 with respect to the transvaginal mesh products  
3 that you have implanted?

4 MR. BARTON:

5 Object to the form.

6 A Yeah. I -- I would not be able to  
7 hazard a guess on what my complication rate is.  
8 I think it's -- it's a -- you know, it would be  
9 considered a very acceptable rate, but I -- I  
10 don't know specifically what it would be.

11 MS. WATKINS:

12 Q Okay. In your practice, do you perform  
13 mesh excision procedures?

14 A I do.

15 Q Okay. And do you perform mesh revision  
16 procedures?

17 A I do.

18 Q And just for the sake of the jury, can  
19 you explain the difference between an excision  
20 procedure and a revision procedure?

21 A Certainly. A revision procedure would  
22 be a procedure where there may be a --

23 Two, I guess, cases that would be  
24 representative would be a small mesh exposure in

1 which case you could excise that exposure and  
2 then close the tissue back over that defect and  
3 leave the bulk of the mesh to do the job and  
4 provide the function for which it was implanted;  
5 whereas, a --

6 What was the term you used for --

7 Was it a --

8 Q **A revision?**

9 A Versus --

10 Q **Excision.**

11 A Excision. So the excision would be  
12 where the product was being removed or at least a  
13 significant part of the product was being  
14 removed. And the most notable examples of that  
15 would be if there were -- for example, with  
16 the -- with the midurethral sling, if the sling's  
17 too tight and the patient's complaint is  
18 difficulty emptying her bladder, then one of the  
19 things that we do is just go in and transect the  
20 sling, which loosens it a little bit, but it  
21 leaves the bulk of it -- leaves the entirety of  
22 it in, but just loosening it that way usually  
23 provides relief to where they're voiding normally  
24 but preserves the function of preventing stress

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1 incontinence.

2 Q Okay. And do you have an estimate as  
3 to how many mesh excision procedures you have  
4 performed?

5 A I don't.

6 Q Do you think it's over a hundred?

7 A Yes.

8 Q Over two hundred?

9 A Well, probably. But I -- you know,  
10 over the course of years, I really don't have an  
11 accurate way to estimate that.

12 Q Okay. But you think it's --

13 A Certainly over a hundred.

14 Q Okay. And what about mesh revision  
15 procedures? Do you have an estimate as to how  
16 many of those you've performed?

17 A That would be over a hundred as well.

18 Q Okay. And do you believe that you have  
19 excised and revised mesh from both the TVT line  
20 of products and the Prolift line of products?

21 A I have.

22 Q Okay. And what are the reasons, in  
23 your practice, why you've recommended mesh  
24 excision and revision procedures to your

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1 patients?

2 A Well, it goes back to my answer  
3 earlier. There are a variety of reasons. It can  
4 be difficulty voiding. It could be mesh  
5 exposure. It could be discomfort or pain with  
6 intercourse. I think those would be -- those --  
7 that would represent the majority of reasons.

8 Q Okay. And this is a little bit of a  
9 similar question, and I apologize if it seems  
10 somewhat repetitive, but what complications  
11 caused by transvaginal mesh have you seen in your  
12 practice?

13 A Are you referring to operative  
14 complications or postoperative complications?

15 Q Postoperative complications.

16 A Okay. So I would say those primarily  
17 fall into those categories that I just said,  
18 either mesh exposure, voiding dysfunction, which,  
19 again, is just difficulty urinating because the  
20 -- a sling may be in too tight, or pain --  
21 usually pain with intercourse.

22 Q Have you, in your practice, seen just  
23 pelvic pain, separate and apart from pain with  
24 intercourse, as a complication associated with

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1 transvaginal mesh?

2 A I have, yes.

3 Q Okay. And you mentioned voiding  
4 dysfunction due to the product's being too tight.

5 Is it your opinion that in those cases that is  
6 surgeon error, or can the product become too  
7 tight after implantation?

8 A I think it's mostly where it was  
9 probably put in a little bit too tight. I think  
10 it's -- I think that's the usual. I don't  
11 think -- I'm not sure that I've seen -- or, if I  
12 have, it's been very, very rare where somebody's  
13 had a sling in for a period of time that's worked  
14 optimally and then suddenly had a voiding  
15 difficulty.

16 Q Do you agree that a woman can develop  
17 mesh complications five or more years after  
18 implantation?

19 A I think the literature says -- it  
20 supports that mesh erosions can occur over time,  
21 and I think that's usually related to other  
22 factors, like vaginal atrophy. It can be related  
23 to -- well, I guess vaginal atrophy is probably  
24 the biggest one. And I think smoking also is a

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1 risk factor for delayed exposures. So I think  
2 there are some variables that enter into that.

3 Q            Okay. Do you agree that a woman can  
4 develop mesh complications ten or more years  
5 after implantation?

6 A            Well, the time frame, I don't -- I  
7 don't think -- I'm not aware that there's  
8 anything saying what number of years. I mean, I  
9 think it can happen probably any time. Again,  
10 it's a function of things that, in my -- in my  
11 mind, are not mesh-related. They're more related  
12 to other things, like vaginal atrophy.

13 Q            Do you agree that it is difficult to  
14 fully remove a transvaginal mesh device from a  
15 woman's body?

16 A            I think it's -- I think it's a surgical  
17 procedure that sometimes can be very difficult.  
18 But I think that, in my -- in my hands, I feel  
19 very comfortable removing whatever needs to be  
20 removed and feel like if I need to remove it, I  
21 can get it. You know, it's not like -- it's not  
22 like you do an operation and it's suboptimal and  
23 that you can't get the mesh that you've gone to  
24 get. Sometimes it takes longer, it's more

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1    technically difficult, but I --

2                    In other words, I find reports of

3    patients who've had mesh excision procedures

4    that -- where it hasn't been removed. And I

5    think that's a function of an inadequate surgery.

6                    But I think that if somebody knows what

7    they're doing and how to do it, that it should be

8    able to be done.

9    Q                Okay. Have you ever been able to fully

10   remove a transvaginal mesh device from a

11   patient's body?

12   A                I have fully removed on maybe two

13   occasions that I can think of where I actually

14   did it through combined incisions of vaginal and

15   retropubic in one case and vaginal and groin

16   incisions in another case. But those were very

17   unusual, and I -- I find -- I find that that is

18   totally unnecessary. And I think the -- I think

19   that the bulk of opinion from physicians who do

20   this kind of surgery would say you remove that

21   part of the mesh that's in contact with the

22   vagina, and as far as dealing with the arms that

23   go distal to -- to the -- to the vagina, there's

24   no merit in removing that.

1 Q Okay. With respect to the two  
2 procedures in which you fully removed a  
3 transvaginal mesh device, would you consider them  
4 complicated procedures?

5 A Not -- no, not necessarily. No.

6 Q Okay. Would you consider them complex  
7 procedures?

8 A No.

9 Q Okay. Bear with me, Doctor. I'm going  
10 through my outline here.

11 Is chronic pelvic pain a risk of the  
12 TVT line of products?

13 A Chronic pelvic pain is a risk of any  
14 vaginal surgery, any pelvic reconstructive  
15 surgery. So it is one of those acceptable risks  
16 that goes along with this -- this specialty.

17 Q Is the same true with respect to the  
18 Prolift product?

19 A Yes.

20 Q Okay. Are there risks associated with  
21 the presence of a properly placed Ethicon  
22 transvaginal mesh product within a woman's  
23 pelvis? What I mean by that is are there risks  
24 associated with the presence of the product

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1 separate and apart from the cervical procedure?

2 A Well, I think what you're alluding to,  
3 is there a risk of mesh as opposed to no mesh in  
4 a surgical procedure? Is that another way of  
5 asking that question?

6 Q I think so. I think we're basically on  
7 the same page. I guess my question is: Is the  
8 presence of the polypropylene mesh from Ethicon's  
9 product within a woman's pelvis associated with  
10 any risk to the woman, separate and apart from --

11 MR. BARTON:

12 I'm gonna object to the form.

13 A I think -- I think the use of mesh  
14 carries its own set of potential problems, which  
15 we've alluded to earlier, in that there's a risk  
16 of mesh exposure. There's, you know -- there are  
17 some inherent risks associated with the use of  
18 mesh, yes.

19 MS. WATKINS:

20 Q Okay. And I don't mean to cover ground  
21 we've already talked about, but you mentioned  
22 exposure. Can that also include erosion into  
23 surrounding organs?

24 A It can include that. I've never

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1 seen --

2 Well, no. I take it back. I've seen a  
3 mesh in the urethra. But I don't think -- I do  
4 not think that that was a function of migration  
5 of the mesh. I think it was a function of an  
6 improper insertion. So --

7 Q Okay.

8 A -- I don't -- I don't believe -- I know  
9 that there are reports of mesh in organs and, you  
10 know, that's something that can happen. But I  
11 think it happens as a result of improper  
12 implantation.

13 Q Okay. So do you believe that there  
14 are --

15 Well, strike that.

16 Do you believe that a properly placed  
17 Ethicon transvaginal mesh product can cause  
18 complications for a woman after implantation?

19 A Well, we've talked about that a little  
20 bit in that, you know, you asked about delayed  
21 erosions down the road. So, yes.

22 Q Okay. Anything aside from delayed  
23 erosions?

24 A I think --

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1 MR. BARTON:

2 Object to the form.

3 A I think that's the -- the primary one  
4 that would be a remote complication, yes.

5 Q Can a properly placed Ethicon  
6 transvaginal mesh product cause urinary  
7 dysfunction after implantation?

8 A Yeah. Again, I mean, we -- we  
9 mentioned that. That would be the reason that we  
10 would do a sling revision --

11 Q Okay.

12 A -- where the mesh was inserted and it's  
13 too tight.

14 Q Can a properly placed Ethicon  
15 transvaginal mesh product cause chronic pelvic  
16 pain for a woman?

17 A It can. But, again, I think that that  
18 goes back to, a lot of times, to the insertion  
19 where it was under too much tension to begin  
20 with.

21 Q Okay. Have you reviewed any medical  
22 literature that has discussed fibrotic bridging  
23 or scar plate formation around transvaginal mesh  
24 after it's been implanted?

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1 A I'm familiar -- I'm familiar with that,  
2 yes. I can't say that I've -- I can't say that  
3 I've seen any articles that specifically address  
4 that.

5 Q **So you've seen it in your practice?**

6 A I've seen -- yeah. I've seen patients  
7 who have had issues with some --

8 I can't remember what the terminology  
9 you used, where --

10 Q **I used fibrotic bridging and scar plate  
11 formation.**

12 A Fibrotic. Yeah. And I think that  
13 usually is a function of the mesh being put in  
14 under too much tension.

15 Q **Okay. And can scar plate that forms  
16 around mesh inside a woman's vagina cause chronic  
17 pelvic pain?**

18 A It can. But, you know, I don't --  
19 I'm -- I'm not sold on the scar plate issue. I  
20 think that with the large-pore monofilament  
21 meshes that are in the Ethicon products, I'm  
22 not -- I have not personally seen a scar plate.

23 And, now, I've seen it on other products, but I  
24 don't think I've seen that on the Gynemesh or

1 Gynemesh PS.

2 Q Okay. Do you have an understanding as  
3 to whether there are differences in the pore size  
4 between the mesh for the Ethicon product versus  
5 the Coloplast Altus product?

6 A Yeah. I'm aware of that.

7 Q Okay. What is the difference in pore  
8 size, if any?

9 A The Ethicon mesh has a considerably  
10 larger pore size.

11 Q Than the Altus?

12 A Than the Altus, yeah.

13 Q Okay. And do you have an understanding  
14 as to what the pore size of the Ethicon mesh is?

15 A You know, I -- I don't specifically  
16 know, but I know that it's greater than 75  
17 microns, because that's kind of the -- that's  
18 kind of the standard for it becoming a  
19 macroporous mesh. And it's considerably larger  
20 than 75 microns.

21 Q Okay. Do you have an understanding of  
22 the weight of the Ethicon mesh?

23 A It's --

24 MR. BARTON:

Charles Hanes, II, M.D.

1 Object to the form.

2 A It -- you know, that's all --

3 I don't -- I don't know in terms of

4 grams per square meter, which I think is the

5 standard for measurement. But I think it's in

6 the intermediate category between lightweight and

7 heavyweight.

8 MS. WATKINS:

9 Q Okay. And do you have an understanding

10 as to the flexibility or stiffness of the Ethicon

11 mesh?

12 MR. BARTON:

13 Object to the form.

14 A I don't -- I don't know any of the --

15 enough about that to really be able to comment.

16 MS. WATKINS:

17 Q Okay. Have you done any lunch or lab

18 research related to polypropylene?

19 A Have I done any lab research related?

20 Q Yes.

21 A I have not.

22 Q Do you consider yourself an expert on

23 polypropylene?

24 A I -- I consider that I have

Charles Hanes, II, M.D.

1 considerable expertise, based on my experience  
2 and based on the multiple laboratory training and  
3 educational events that I've been to.

4 Q Okay. But do you agree that you are  
5 not an expert in materials science?

6 A I -- again, I would say that I have  
7 considerable expertise. I mean, where do you  
8 draw the line of being an expert? I don't know  
9 where that line would be.

10 Q Okay. Have you reviewed the design  
11 specifications for the TVT line of products?

12 A By design specifications, I think I'm  
13 very familiar with those, based on the training  
14 and the corporate events that I attended. They  
15 went into considerable detail about the design  
16 aspects.

17 Q Okay. Would the same be true with  
18 respect to the Prolift product?

19 A Yes.

20 Q And are you an expert in warnings?

21 A In what?

22 Q Warnings.

23 A Warnings?

24 Q Yes.

Charles Hanes, II, M.D.

1 A Like in the IFU? Are you referring to  
2 that?

3 Q Yes.

4 A Yeah, I would say --

5 Again, I mean, I would draw the line.

6 I have considerable expertise because I -- in the  
7 course of training doctors, we discuss those  
8 repeatedly.

9 Q Okay. Have you ever been --

10 Well, strike that.

11 Have you ever drafted a warning for a  
12 medical device or pharmaceutical company's  
13 product?

14 A No, I have not.

15 Q Are you an FDA regulatory expert?

16 A I'm not -- I would go back and frame  
17 that as I'm very familiar and feel like I have  
18 some expertise in FDA dealings. But, again, to  
19 say I'm an expert, I don't know where you draw  
20 the line on that.

21 Q Okay. Have you personally interacted  
22 with the FDA with respect to any medical devices  
23 or pharmaceutical products?

24 A No.

Charles Hanes, II, M.D.

1 Q Okay. Have you published any medical  
2 literature about any of Ethicon's products?

3 A No.

4 Q Okay. I'm almost done, Doctor, so bear  
5 with me here.

6 MS. WATKINS:

7 Lois, do you mind marking as -- I guess  
8 it would be Exhibit 13, maybe?

9 THE COURT REPORTER:

10 Yes, ma'am.

11 MS. WATKINS:

12 There's two items of literature there.

13 One it titled "Evaluation and Management of  
14 Midurethral Sling Complications."

15 THE COURT REPORTER:

16 Right.

17 MS. WATKINS:

18 If you don't mind marking that as an  
19 exhibit and then the ACOG Practice Bulletin as an  
20 exhibit and letting me know what those numbers  
21 are, I'd appreciate it.

22 THE COURT REPORTER:

23 Okay. In that order, Number 13, and,  
24 then, ACOG is 14.

Charles Hanes, II, M.D.

1 MS. WATKINS:

2 Thanks.

3 (EXHIBITS 13 AND 14 WERE

4 MARKED FOR IDENTIFICATION.)

5 MS. WATKINS:

6 Q Okay. Doctor, we've marked as Exhibit  
7 13 an April 2016 article titled "Evaluation and  
8 Management of Midurethral Sling Complications."

9 Do you have that in front of you?

10 A I do.

11 Q Okay. Have you seen this document  
12 before?

13 A I think I have. I'm pretty certain I  
14 have.

15 Q Okay. Did you review it in forming  
16 your opinions in this litigation?

17 A I'm not sure if this is one of them  
18 that I reviewed in -- specifically in this  
19 litigation.

20 Q Do you know whether this is on your  
21 reliance list that we've marked as an exhibit  
22 here today?

23 A I don't know that.

24 Q Okay. If you don't mind turning to the

1 second page of that. And I want to look at  
2 the -- on the left column, the first full  
3 paragraph. I'm gonna read something and ask you  
4 whether you agree with that.

5 Are you on the second page, Doctor?

6 A I am.

7 Q Okay. I'm gonna read the  
8 paragraph or -- excuse me -- the sentence that  
9 starts with "nonetheless."

10 A Okay.

11 Q "Nonetheless, certain complications  
12 from midurethral sling surgery are unique to the  
13 use of polypropylene mesh. These can include  
14 mesh exposure, chronic pelvic pain, and  
15 dyspareunia, which are the most common, as well  
16 as mesh contracture, organ perforation, and/or  
17 neuromuscular injury."

18 Do you agree with that statement?

19 A Um, I don't -- you know, I don't think  
20 that those complications are unique to the use of  
21 polypropylene mesh. In other words, chronic  
22 pelvic pain and dyspareunia is -- is a notable  
23 complication of any pelvic reconstructive  
24 surgery. Organ perforation, also, and

Charles Hanes, II, M.D.

1 neuromuscular injury for reconstructive surgery.

2 Q Okay. The next sentence reads: "Other  
3 complications may include de novo urgency and/or  
4 urgency urinary incontinence, urinary tract  
5 infection, and/or urinary obstruction."

6 Do you agree with that sentence?

7 A Well, those are complications that can  
8 occur with midurethral slings. But, again, they  
9 can occur with other operations that are for the  
10 correction of incontinence. And, in fact, I  
11 think those complications are probably more  
12 frequent with the Burch procedure.

13 Urinary tract infections accompany most  
14 every operation in which an in-dwelling Foley  
15 catheter was inserted.

16 Urgency incontinence is a frequent  
17 accompaniment of any kind of incontinence  
18 surgery.

19 So I don't -- I don't think any of  
20 those are specific to midurethral sling. They  
21 certainly can happen with midurethral sling.

22 Q Okay. If you don't mind turning to the  
23 second-to-last page of that document. And in the  
24 left-hand upper portion of that, it says

Charles Hanes, II, M.D.

1 "Conclusions." If you don't mind letting me know  
2 when you're there, Doctor, I appreciate it.

3 A Oh, yeah. I've gotcha.

4 Q Okay. Good.

5 The first sentence reads,

6 "Complications from midurethral slings are not  
7 rare."

8 Do you agree with that statement?

9 A I think that -- I don't know what the  
10 definition of "rare" would be. I mean, there's  
11 certainly complications that go along with any  
12 surgery. So I don't -- I think that's a vague  
13 statement.

14 Q Okay. And, then, two sentences down,  
15 it states, "However, if a patient does have  
16 post-operative concerns, providers should have a  
17 high index of suspicion for mesh-related  
18 complications."

19 Do you agree with that statement?

20 A I think that if -- if mesh is used, as,  
21 obviously, this is talking about the midurethral  
22 sling, so there are certain complications that  
23 are specific to mesh, but there are also  
24 complications that are -- that accompany any

1 surgery for the correction of incontinence.  
2 So, yeah. I mean, I think you have to  
3 be aware of the peculiar mesh-related potential  
4 complications and be knowledgeable about those.  
5 Q Okay. The next sentence reads, "The  
6 management of midurethral sling complications is  
7 challenging and may warrant referral for  
8 specialist care. Unfortunately, these  
9 complications are not always reversible and can  
10 be quite debilitating for patients."

11 Do you agree with that statement?

12 A By and large, I --  
13 I'd have to break it up. I think that  
14 for the general OB-GYN practitioner, I think a  
15 lot of them are not comfortable or would not be  
16 the right ones to do a mesh excision, a  
17 midurethral sling excision.

18 As far as the reversibility, I think  
19 that if an adequate excision -- if an excision is  
20 indicated and if an adequate excision is  
21 performed, in my experience, I'm not -- I'm not  
22 convinced that I've ever seen anybody that has  
23 not -- where their symptoms have not been  
24 reversible.

Charles Hanes, II, M.D.

1 Q Okay.

2 A I suppose there are --

3 I don't -- you know, I wouldn't want to

4 make that a universal statement. I'm sure there

5 may be exceptions, but -- but I think it's rare.

6 Q Okay. And, Doctor, you can set that

7 one aside, please.

8 And, then, if you don't mind moving on

9 to Exhibit 14, the ACOG Practice Bulletin dated

10 November 2017 --

11 A Uh-huh. Okay.

12 Q -- regarding pelvic organ prolapse.

13 A Yes.

14 Q Do you have that in front of you?

15 A Yes.

16 Q And, Doctor, are you a member of ACOG?

17 A I am.

18 Q Okay. And have you seen this document

19 before?

20 A I have.

21 Q Okay. And are you also a member of

22 AUGS?

23 A I am.

24 Q Okay. If you don't mind turning to, on

1 the bottom right corner -- I guess it's the only  
2 one that has a number on it, it's E243.

3 A Yeah, I'm there.

4 Q Oh, you are. Good.

5 All right. This is under the section  
6 that reads "What are the complications of pelvic  
7 organ prolapse surgery and how are they managed?"

8 A Yes.

9 Q And I'm gonna read from the second full  
10 paragraph under that section and then ask you to  
11 agree with some of those sentences.

12 "There are unique complications  
13 associated with synthetic mesh when they are used  
14 in pelvic organ prolapse surgery. These include  
15 mesh contracture and erosion into the vagina,  
16 urethra, bladder, and rectum."

17 Do you agree with those statements?

18 A Again, I would -- I would have to  
19 disagree with the whole mesh contracture thing.

20 I --

21 In principal, you know, I think it's  
22 more accurate to say scar contracture. And that  
23 goes back to our discussion earlier. I think  
24 once the mesh is in place, within two weeks you

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1 have tissue incorporation into the mesh, and,  
2 therefore, the mesh itself can't contract. It's  
3 the scar that contracts. And the scar  
4 contracture is a function of a surgical incision  
5 and not -- and not of the mesh. And that's my  
6 opinion and that's my experience.

7 As far as erosions into the vagina,  
8 that's, you know, what we talked about earlier  
9 with mesh exposure.

10 With POP surgery, I've never seen  
11 erosion into the urethra. As I mentioned  
12 earlier, I saw a transurethral sling, but I think  
13 that was a function of improper insertion. But  
14 I've never seen that with the POP surgery. And  
15 I've never seen erosion into the bladder or  
16 rectum.

17 Again, I think that if -- if that  
18 occurs, it more than likely is a function of  
19 improper insertion as opposed to migration. I  
20 don't -- I do not believe it's possible for mesh,  
21 once it's integrated with tissue, to migrate  
22 anywhere.

23 Q Okay. Are you familiar with any  
24 medical literature indicating that a properly

1 placed transvaginal mesh product can migrate  
2 after implantation?

3 A No. That's what I say. I don't  
4 believe that's possible.

5 Q Okay. The next sentence reads, "The  
6 rate of mesh erosion is approximately 12 percent  
7 after vaginal mesh prolapse surgery."

8 Do you agree with that statement?

9 A I think that's a -- that's a figure  
10 that is debatable. I mean, I think there --  
11 there are figures that are tossed out, and I've  
12 seen figures ranging from 5 percent or even as  
13 low as 3 percent in some series. But I think 12  
14 percent would be upper limits.

15 Q Do you have any reason to disagree with  
16 that number?

17 A Well, I don't know -- you know, I don't  
18 know where they got that number. If it's a  
19 meta-analysis over a voluminous amount of  
20 reports, then I wouldn't refute that.

21 Actually, they reference it as number  
22 41, so let's see what it says. So 41 says --

23 Oh, that's -- yeah. That's the  
24 systematic review. And I think that was in the

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1   Cochrane database. So, you know, I think that's  
2   certainly reputable.

3                   But I -- I think that the -- probably  
4   the difficulty with that figure is that it  
5   doesn't take into account the experience of the  
6   users, its multiple users and those with lots of  
7   experience and also those with very little. So  
8   I, in my opinion, I think that number's high.

9   Q               Okay. And, then, the next sentence  
10   reads, "When mesh is used for anterior vaginal  
11   wall prolapse repair, there is an 11 percent risk  
12   of mesh erosion, with 7 percent of these cases  
13   requiring surgical correction."

14                 Do you have any reason to disagree with  
15   those numbers?

16   A               Again, I kind of resort to the -- my  
17   same answer. I -- I think to say that using mesh  
18   in the anterior compartment is gonna subject  
19   somebody to 11 percent risk of erosion is  
20   probably not an accurate statement if it comes  
21   from somebody that's experienced. In fact, I  
22   know plenty of doctors who routinely use mesh in  
23   the anterior compartment and don't have exposure  
24   rates near -- near like that.

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1                   So I think when you're taking the --  
2   the bulk of the literature and taking all users  
3   and coming up with a cumulative number, I'm not  
4   gonna say that's not accurate, but I don't think  
5   it reflects the experience of experienced users.  
6   Otherwise, I don't think they'd be putting it in.

7   Q               Okay. And the next sentence reads,  
8   "The rate of dyspareunia is approximately 9  
9   percent after vaginal mesh prolapse surgery."

10                  Do you agree with that number?

11   A               I think that -- that may be a good  
12   number. But, also, I think that you can find  
13   numbers that are comparable and sometimes even  
14   higher with other pelvic reconstructive  
15   procedures. The posterior repair, for example,  
16   is notorious for causing dyspareunia, and that's  
17   a native tissue repair. So, yeah.

18   Q               Okay. And the last sentence I'm gonna  
19   ask you about is what reads: "Multiple  
20   procedures often are required to manage  
21   mesh-related complications."

22                  Do you agree with that statement?

23   A               I think that in a lot of cases it has  
24   required multiple procedures. But, again, I

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1 would -- I would say in the hands of somebody  
2 that's experienced in doing this type of surgery,  
3 that it's rare that one procedure is not going to  
4 provide the benefit that you're looking for.

5 Q           Okay. Doctor, I don't believe I have  
6 any additional questions. Thank you for your  
7 time. And, again, I'm greatly sorry for being  
8 late today.

9 A           Well, it's perfectly all right. And I  
10 appreciate your being polite over the telephone.

11 MR. BARTON:

12           Can we go off the record for a second,  
13 Diane?

14 MS. WATKINS:

15           Sure.

16           (OFF THE RECORD.)

17           EXAMINATION

18 BY MR. BARTON:

19 Q           Doctor, in previous examination by  
20 plaintiffs' counsel today, she referred you to a  
21 sentence in one of your -- the consulting  
22 agreements with Ethicon, and the sentence reads,  
23 "You shall not make any representation relating  
24 to Company's products or to Company's clinical

1   outcomes unless such representations have been  
2   reviewed and approved in advance by Company."

3                   Did I read that correctly?

4   A               Yes.

5   Q               Did that sentence and that part of the  
6   consulting agreement, in your recollection, ever  
7   come into play in your performance as a  
8   consultant for Ethicon? And, if so, how?

9   A               I don't think it came into play. I  
10   mean, I think -- the way I -- the way I construe  
11   that is that in these formal  
12   training/preceptor/visiting doctor relationship,  
13   that I needed to utilize the materials, the  
14   PowerPoint, the IFU, and stay on point with that.  
15   It didn't -- it didn't preclude me from going off  
16   label at times. If somebody asked me a question,  
17   I -- I was free to give them my opinion. And I  
18   can't say -- I mean, there were times maybe it  
19   wasn't off label.

20                  But I never -- I never did deviate from  
21   saying my opinion and never, even when company  
22   representatives were there, which they frequently  
23   were --

24                  The representatives were there during

1 these training sessions a lot of times, and, you  
2 know, that was never an issue.

3 MR. BARTON:

4 That's all I have.

5 MS. WATKINS:

6 No questions.

7 (Deposition concluded at 11:55 a.m.)

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1 C E R T I F I C A T E

2 STATE OF ALABAMA)

3 COUNTY OF MOBILE)

4

5 I do hereby certify that the above and  
6 foregoing transcript of proceedings in the matter  
7 aforementioned was taken down by me in machine  
8 shorthand, and the questions and answers thereto  
9 were reduced to writing under my personal  
10 supervision, and that the foregoing represents a  
11 true and correct transcript of the proceedings  
12 given by said witness upon said hearing.

13 I further certify that I am neither of  
14 counsel nor of kin to the parties to the action,  
15 nor am I in anywise interested in the result of  
16 said cause.

17 Signed this 15th day of July, 2019.

18

19

Lois Anne Robinson

LOIS ANNE ROBINSON, RDR

20

COURT REPORTER, NOTARY PUBLIC

STATE OF ALABAMA AT LARGE

21

ACCR# 352; EXPIRES 9/30/19

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24

1 E R R A T A P A G E

2

3 I, CHARLES HANES, II, M.D., the witness  
4 herein, have read the transcript of my testimony,  
5 and the same is true and correct, to the best of my  
knowledge, with the exceptions of the following  
5 changes noted below, if any:

6	Page/Line	Change	Reason
7	_____	_____	_____
8	_____	_____	_____
9	_____	_____	_____
10	_____	_____	_____
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22 CHARLES HANES, II, M.D.

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2 DECLARATION OF WITNESS

3

4 I, the undersigned, declare under penalty  
5 of perjury that I have read the foregoing  
6 transcript, and I have made any corrections,  
7 additions, or deletions that I was desirous of  
8 making; that the foregoing is a true and correct  
9 transcript of my testimony contained herein.

10 EXECUTED this \_\_\_\_\_ day of \_\_\_\_\_,  
11 2019, at \_\_\_\_\_, \_\_\_\_\_.

(City)

(State)

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17 CHARLES HANES, II, M.D.

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